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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/574,114

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Adam Bruce

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7428

30/593

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12/09/2009

HARNESS, DICKEY & PIERCE, P.L.C.

P.O. BOX 8910

RESTON, VA 20195

EXAMINER

GOUGH, TIFFANY MAUREEN

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

12/09/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/574,114

**Applicant(s)**

BRUCE ET AL

**Examiner**

TIFFANY M. GOUGH

**Art Unit**

1657

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 7-10 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 11-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/GS/US)  
Paper No(s)/Mail Date 5/21/09
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's response filed 7/10/2009 has been received and entered into the case. Claims 1-14 are pending. Claims 7-10,14 have been withdrawn. All arguments and amendments have been considered. Claims 1-6,11-13 have been considered on the merits.

#### ***Priority***

**As stated in the previous Office Action**, receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. Priority is granted to 10/2/2003.

#### ***Drawings***

The previous objection to the drawings has been withdrawn in light of applicants amendment to the specification.

#### ***Specification***

The previous objection to the disclosure because of the following informalities: the arrangement of specification does follow the suggested guidelines, in particular there is no Brief Description of Drawings or Cross-References to Related Applications, such as priority documents, is withdrawn in light of applicants amendment to the specification.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The previous rejections of record under 35 USC 112, second paragraph, have been withdrawn due to applicants claim amendments. It is also noted that claims 7 and 9 are withdrawn.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of each of Antananvich et al. (US 6372244 B1) and Brauker et al. (US 5782912) in view of Wang et al. (US 2003/0153981 A1).

Applicants claim a bioartificial implant comprising a semipermeable barrier having a surface coating of a bioactive metal which does not interfere with the semipermeability of the semipermeable barrier. The barrier allows or prevents diffusion of substances, material and molecules to the opposite side of the barrier. Applicants also claim the surface coating to be a net of bioactive metal such as titanium which has been applied by an atomizing process.

Antananvich teach an implant comprising a semipermeable barrier containing a coating which allows or prevents diffusion of substances, material and molecules to the opposite side of the barrier (abstract, col.19, lines 10-20, col. 20, lines 55-61, col.21, lines 27-28). The substances are produced in a human or animal body, i.e., cells (col. 19, lines 50-53, col. 21, lines 13-20).

Brauker teach an implant comprising a coated semipermeable barrier (col.14., lines 15-17) which allows or prevents diffusion of substances, material and molecules to the opposite side of the barrier (col.3, lines 55-60, col. 4, lines 8-12, col. 6, lines 53-68, col. 7, lines 40-45 ). The substances are produced in a human or animal body, i.e., blood sugar (col. 13, lines 64-68). The implant further comprises a sensor element enclosed by a membrane (col.5, lines 37-42, col. 13, lines 64-col. 14, lines 1-20). The sensor is disclosed as being a blood sugar detecting sensor element (col. 13, lines 64-col. 14, lines 1-20). Brauker also contemplates that the sensor can be coated with a material which circumvents the problem of foreign body occlusion and that materials such as metals could be used if manipulated to provide three dimensional structures (col. 14, lines 1-20).

Antanavich and Brauker do not teach coating with a bioactive metal such as titanium, zirconium, tantalum or alloy.

Wang et al (US 2003/0153981 A1) teach bioartificial implants which have been coated with metals such as titanium, alloy or tantalum (0032, 0084) by spraying (0090) and low temperature arc vapor deposition. i.e. atomizing process' (0023, 0034-0036, 0042,0090).

At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to have coated the semipermeable membrane implant of Antananvich and Brauker with a bioactive metal such as those disclosed by Wang because the claimed coatings are known in the art as being useful as coatings on implants as well as have excellent biocompatibility because it resists tissue growth on its surface, regardless of the surface they are deposited on, i.e. a metal surface or a semipermeable surface. Further such metals provide a mechanical support for the implant. i.e. rigid enough to withstand deformation once implanted. Further, Antananvich clearly teaches a need for a biocompatible implant which allows nutrient diffusion further disclosing the need for biocompatible materials to enclose the implant which are non-toxic and non-fibrogenic (col. 3, lines 20-col. 4, lines 1-35, col. 21, lines 14-20).

Thus, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to have coated the implant of Antananvich with a bioactive metal with a reasonable expectation for successfully providing a biocompatible implant because Antananvich clearly teaches a need for a biocompatible implant which allows nutrient diffusion further disclosing the need for biocompatible materials to enclose the implant which are non-toxic and non-fibrogenic. It is known in the art, see Wang, that implants can be coated with titanium by an atomizing process. Titanium is known to have excellent biocompatibility because it resists tissue growth on its surface and it further provide a mechanical support for the implant. i.e. rigid enough to withstand deformation once implanted. Employing a known coating for its known function with the expected results would have been obvious.

The above references do not teach the claimed form or coating thickness.

However, it would have been obvious to one of ordinary skill in the art to optimize such result effective variables as routine optimization. And the form or thickness of the coating is a mere design choice where no functional advantage is seen.

### ***Response to Arguments***

Applicant's arguments with respect to the Okazaki reference have been considered but are moot in view of the new ground(s) of rejection because Okazaki has been removed from the rejection of record under 35 USC 103(a).

Applicants arguments with respect to the Wang reference have been considered. Applicant argues that Wang teaches away from the claimed invention because the techniques disclosed by Wang are only possible when using a metal substrate and the high temperature deposition method of Wang would decompose the implant.

It is the Examiners position that Wang clearly teaches using an atomizing process to apply metal to an implant. Wang teaches low temperature arc vapor deposition and spraying methods to apply a metal "skin network" to the implant. Therefore, the application method for applying a metal coating onto an implant such as that taught by Wang, can be used to apply a metal coating on an implant such as that disclosed by Antanavich and Brauker without the high temperature treatment step and negative effect on the semipermeability of the implant argued by applicant.



***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIFFANY M. GOUGH whose telephone number is (571)272-0697. The examiner can normally be reached on M-F 8-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Majunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ralph Gitomer/  
Primary Examiner, Art Unit 1657

/Tiffany M Gough/  
Examiner, Art Unit 1657